UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

MAR 30 2000

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

Mary Beth Sweetland, Vice President
People for the Ethical Treatment of Animals
501 Front Street
Norfolk, VA 23510

Dear Ms. Sweetland:

On December 27, 1999, EPA received your petition under Section 21 of the Toxic Substances Control Act (TSCA) on behalf of People for the Ethical Treatment of Animals (PETA) and on behalf of four other organizations. The petition requests that EPA initiate TSCA rulemaking proceedings with respect to all chemicals included on the HPV (High Production Volume chemical) Challenge Program list as updated through the date of initiation of the requested proceedings. Specifically, the petition requests that EPA issue (1) a TSCA Section 8(a) Preliminary Assessment Information Reporting (PAIR) rule and (2) a Health and Safety Data Reporting rule under TSCA Section 8(d). While we support the underlying objective to eliminate unnecessary testing behind your petition, we must deny the request to accomplish this objective through a new rulemaking under Section 8 of TSCA. EPA will publish in the next few days a **Federal Register** notice which announces EPA's response to this TSCA Section 21 citizens' petition.

EPA agrees with your petition's general premise that relevant extant hazard data (both "positive" data that indicate an effect and "negative" data that do not indicate an effect) on the HPV Challenge Program chemicals should be made available before any screening-level hazard testing (animal or non-animal) under the HPV Challenge Program or associated test rule(s) is conducted. The HPV Challenge program is built on this very premise and, as you know, is further demonstrated in EPA's October 14, 1999, guidance to HPV Challenge participants. I want to stress the comprehensive nature of the search for and review of existing toxicity studies that is occurring and will occur for each of the chemicals in the HPV Challenge program and any other chemicals listed under associated HPV test rules.

As you also know, EPA is firmly committed to reducing and eliminating, where possible, the use of animals during any HPV chemical testing that must be conducted. EPA works domestically within the framework of the Interagency Coordinating Committee for the Validation of Alternative Methods (ICCVAM) and internationally with the Organization for Economic Cooperation and Development (OECD) to ensure the scientific acceptability of alternative test

methods. Test methods must be scientifically validated and be accepted for regulatory and international data sharing purposes.

Granting a petition under TSCA Section 21(b)(4)(B)(ii) for rulemaking under Section 8 is not required unless the petitioner establishes that *"there is a reasonable basis to conclude that the issuance of such a rule or order is necessary to protect health or the environment against an unreasonable risk of injury to health or the environment."* The petition does not present an argument that the requested rules are necessary to protect health or the environment, but only asserts that the TSCA Sections 8(a) PAIR and 8(d) rules provide a more efficient and effective approach to obtaining existing screening-level hazard data on HPV Challenge Program chemicals. As stated above, the collection of these data is already a fundamental part of both the HPV Challenge program and associated test rule(s) and we strongly believe that all stakeholders in the HPV Challenge Program share the goal of avoiding unnecessary testing, in particular the participants who are and will be gathering and making publicly available extant test data and only developing data where screening level data are needed.

In addition, EPA believes that promulgating rules under TSCA Sections 8(a) PAIR and 8(d) are not necessary to fulfill the objectives of the HPV Challenge Program for the following reasons:

- submissions under the requested regulations would substantially duplicate data needs of the HPV Challenge Program that participants are already committed to providing and have an incentive to provide;

- the requested regulations would be a less effective and efficient means to gather extant screening-level hazard data on HPV chemicals than the HPV Challenge Program, which is similar to the internationally accepted OECD Screening Information Data Set (SIDS) program; and

- the burden associated with the requested regulations outweighs any benefit that might derive from them.

Finally, I want to assure you that EPA is not opposed to the admirable goals of the many groups devoted to advocating for and advancing the welfare of animals. However, we must balance those goals with the responsibility given us by Congress to protect the environment and the health of the American people from the hazards, both known and unknown, posed by toxic substances in commerce. We keenly recognize that new and revised toxicological test methods are being developed with increasing frequency, and scientists around the world are incorporating recent advances in molecular and cellular biology as well as new research technologies, into their work. These developments hold great promise for further reduction of animal use in the future.

I look forward to continuing to work with you and other members of the animal advocacy community as we move forward with providing the American public with needed information about the chemicals that they come in contact with everyday but doing it in such a way that we avoid even one unnecessary or duplicative test.

Sincerely,

Susan H. Wayland

Susan H. Wayland
Acting Assistant Administrator

cc: Jessica Sandler (PETA)
Mindy Kursban (PCRM)
Sara Amundson (DDAL)
Marc Berman (IMMP-EIS)
Marcia Kramer (NAVS)
Docket # OPPTS-211044